IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	Case No. 1:14-cv-1748 MDL No. 2545 Hon. Matthew F. Kennelly
THIS DOCUMENT RELATES TO ALL CASES	

MEMORANDUM IN SUPPORT OF
PLAINTIFFS' PROPOSED UNIFIED CASE MANAGEMENT PLAN

I. Introduction

The PSC respectfully submits this memorandum in support of its proposed Unified Case Management Plan. (Attached hereto as Exhibit A is a copy of the PSC's proposed plan.) The PSC's Unified Case Management Plan aims to provide reasonable deadlines designed to move this litigation forward toward trial in a logical and timely manner. The PSC's plan proposes that the first six initial bellwether trials would take place between June 15, 2016 and January 31, 2017. With the initial trial date of June 15, 2016 in mind, the PSC's plan provides for all dispositive motions to be fully submitted to the Court by May 16, 2016, a full month before the first trial would be set to begin.

Similarly, the PSC's plan establishes an approximately four-month period between April 29, 2015 and August 28, 2015, for the parties to conduct bellwether fact discovery, during which time generic liability discovery will also be ongoing. Generic liability discovery of the Defendants will be conducted throughout the remainder of 2014, 2015, and perhaps into 2016, as needed. Fact discovery will be followed by expert discovery in early 2016. This sequence of events,

comprehensive fact discovery (both bellwether and liability), expert discovery, and dispositive motions followed by trial is the common custom and practice of most major pharmaceutical mass tort cases.

Despite the fact that this general framework is almost always agreed upon between the parties negotiating case management plans, over the past few weeks Defendants have flatly rejected this typical discovery plan and trial schedule without offering any valid basis for doing so. The parties have engaged in discussions concerning the scheduling of discovery, and more generally, the overall framework of a proposed Unified Case Management Plan. It is clear from this meet and confer process that there are fundamental differences between the parties' respective proposed case management plans that have rendered resolution of these issues without Court intervention an impossibility. (Attached hereto as Exhibits B, C, and D are Defendants' first, second and third draft Unified Case management Plans, respectively.)[1]

Each version of Defendants' proposed Unified Case Management Plans suffers from three major flaws that stem from Defendants' myopic desire to have the parties and this Court focus efforts solely on the issue of general causation to the exclusion of all other relevant issues. Defendants' proposal would not save any time and should not be adopted. The Defendants' proposal to conduct discovery on the issue of general causation before all others is merely an attempt to delay the timely resolution of this litigation. First, Defendants' proposed plan provides that only general causation discovery may be conducted and the issue ruled upon by the Court prior to any other discovery being undertaken. This means halting discovery relating to the

[1] The PSC proposal was tendered to Defendants on September 12, 2014. The Defendants finally provided an outline version of a proposal on October 6, 2014 (after extensive requests by the PSC to engage in this process) in the form attached hereto as Exhibit B, and then amended their outline proposal, in the form attached hereto as Exhibit C, on October 13, 2014. Thereafter, late in the evening on October 14, 2014, Defendants provided a more robust version of their outline, in the form attached hereto as Exhibit D, but have not tendered the same on behalf of all Defendants.

regulatory approval process and the extensive and critical issues surrounding the sales and marketing of the testosterone products, and, equally importantly, does not allow for any plaintiff/bellwether case-specific discovery to go forward until this general causation discovery period is complete. This is an extraordinarily inefficient schedule as it will exponentially increase the time it will take the parties to complete pretrial proceedings. Additionally, this delay greatly prejudices Plaintiffs, who would be forced to wait significantly longer for their day in Court before being able to obtain any redress for their injuries.[2]

Second, in addition to the delays that will result from failing to conduct all discovery (liability and plaintiff/bellwether) concurrently with the proposed general causation-only discovery, Defendants' thinly-veiled attempt to avoid production of non-general causation discovery forces the PSC to accept Defendants' interpretation of what constitutes "general causation discovery." To this end, in each draft of their proposed Unified Case Management Plans, Defendants identify certain areas of discovery that they contend constitute general causation discovery (*e.g.*, Research & Development, Regulatory Affairs, Safety, and Pharmacovigilance). However, this is extremely problematic because there are countless examples of mass tort pharmaceutical MDLs wherein critical liability documents relating to causation have been discovered in the custodial files of personnel in other departments or business units, including upper and lower level sales and marketing personnel and/or revealed during these individual's depositions.[3]

[2] As noted below, the Defendants' timeline to complete general causation discovery and file their general causation motions is approximately the same timeline as the PSC proposes in which the parties can complete all discovery and complete both general and case-specific *Daubert* motions on all issues (and thereafter be trial ready with actual plaintiff's cases).

[3] As noted in section II, *infra*, getting the defense to engage in advancing this ball forward (or at least a certain defendant) has been extremely frustrating.

In many instances, the most candid discussions about a company's knowledge of the risks of a product and other documents relevant to general causation are contained in emails and other materials that can be considered budgeting, corporate planning or sales and marketing documents (including evidence regarding what and when a company knew information, and what personnel were being instructed to say, *and more importantly what they were told not to say*, both to consumers and the medical community) sent and received by members of the sales force as well as members of the marketing teams that launch and maintain these products in the marketplace.[4] It would be extraordinarily inefficient to engage in document and deposition discovery of these employees and attempt to circumscribe document production and depositions to the issue of general causation. Moreover, not having access to this information would severely prejudice the Plaintiffs and the PSC, and not leave the Plaintiffs on equal footing as the defense.

Third, as noted above, Defendants' proposed case management plans provide for bellwether discovery to commence only after the completion of general causation discovery. More specifically, when general causation discovery is complete, then other generic discovery against the Defendants as well as bellwether discovery can start, with each area of discovery essentially being done in separate and distinct stages. This simply is not logical. There are no compelling or even valid reasons why the parties cannot engage in a bellwether discovery process that takes place concurrently with the discovery related to Defendants' liability as well as general causation. These

[4] The fact that Defendants in this case do not want to turn over sales force documents only reinforces Plaintiffs' concern, based on prior experience, that critical documents are likely to be found in the custodial files of non-general causation custodians (*e.g.*, sales and marketing personnel). The marketing and promotion aspect of this case is integral to the overall theory of liability, because the drug was aggressively marketed for off-label uses for which there was no evidence that it provided any benefit whatsoever. The evidence gathered to date, before any discovery has begun, shows that any risk of injury from testosterone is unacceptable, because it does not confer any benefit to the target population of the extensive direct-to-consumer marketing campaign engaged in by Defendants. As such, the marketing aspect of this case is inextricably linked the overall theory of liability and cannot be "bifurcated" from general causation.

three areas of discovery, namely bellwether discovery, general causation and generic liability are not entirely distinct areas of inquiry, and the discovery process with respect to each often informs and explains the other areas.[5]

Finally, Defendants have provided no reason why this litigation should be conducted so vastly differently than the overwhelming majority of mass tort litigations that follow the general framework proposed by the PSC, or why this Court should diverge from accepted and established procedure.

Entry of a Unified Case Management Plan is time-sensitive. To date, the PSC has not received a single document from Defendants, and has not been able to extract even the most basic items in a pharmaceutical case such as the NDA/INDA (despite requesting this informally and formally for over a month).[6]

Against this backdrop, the Court should adopt Plaintiffs' proposed Unified Case Management Plan.

II. Plaintiffs' Proposed Unified Case Management Plan

A. General Framework of the PSC's Unified Case Management Plan

The PSC's proposed plan will ensure that the Court renders well-informed decisions regarding general causation, as well as all other contested issues, that are based on all the potentially relevant documents and deposition testimony, not just those that Defendants

[5] Indeed, the fact that discovery of a defendant is even being addressed as two components is far from the norm and is a notion that has been manufactured by the AbbVie Defendants in their proposal.

[6] The NDA/INDA is essentially the application that a drug company submits to the FDA in order to get approval to market the drug in the United States for specific FDA-approved indications. It is something that drug manufacturers are required to maintain in the usual course of business and can be easily produced to the plaintiffs; typically in a matter of days (not over a month as has been the case here).

subjectively determine are relevant to the issue of general causation. The PSC's plan, summarized below and attached as Exhibit A, provides for an efficient schedule for the selection of representative bellwether cases, discovery in those bellwether cases, and realistic trial dates calculated to result in the efficient resolution of this litigation as a whole, thereby serving the very purpose of multidistrict litigation. By undertaking all discovery at the same time, the parties are able to minimize the burden on judicial resources, set realistic trial dates in a timeframe that allows the Plaintiffs to have full and fair access to the courts, and which is not obstructed by Defendants' obfuscating tactics in this regard. Notably, the PSC's plan also provides for the issue of general causation to be resolved in a timely and logical manner, *i.e.*, at the end of discovery.

Pursuant to CMO No. 9, Plaintiff Fact Sheets for all cases on file as of the date of the Order are due December 29, 2014, and Plaintiff Fact Sheets for all cases filed after the date of CMO No. 9, are due 45 days after the last Defendant's Answer is filed. As set forth in greater detail in Exhibit A attached hereto, the PSC's Unified Case Management Plan proposes the following schedule:

Bellwether Fact Discovery:[7]

Under the PSC's Case Management Plan:

- By March 27, 2015, the parties would submit a case management order that proposes a methodology for selecting (with the Court's involvement) which of the filed cases should be selected as initial trial or bellwether cases.[8]

- Between April 29, 2015 and August 28, 2015, core bellwether discovery shall take place, with a maximum of four (4) depositions per side for each case.

- On or before September 15, 2015, the parties will, in accordance with a CMO that is submitted on or before March 27, 2015, develop a methodology for proposing

[7] As described below, the PSC also submits that the two generally disparate injury categories (thromboembolic injuries versus cardiovascular injuries) be placed into and worked-up in two different sets of bellwether trials.

[8] Plaintiffs propose establishing this methodology in the future to allow the parties the opportunity to receive completed Plaintiff Fact Sheets and accompanying medical records before making a recommendation to the Court on what factors are relevant for selection of bellwether cases.

and selecting (with the Court's involvement) which of the bellwether cases should be selected as initial trial cases. As part of that CMO, each side shall provide the Court with the specified number of bellwether cases from which the trial pool will be selected.

- By October 16, 2015, the Court will select which bellwether cases are to serve as the first three VTE trials and which are to serve as the first three cardiovascular trials plaintiffs, and designate the order of such bellwether trials.

Bellwether Expert Discovery:

- On or before January 15, 2016, Plaintiffs shall designate, pursuant to Fed. R. Civ. P. 26, their expert witnesses and provide their reports for each of the first six (6) bellwether trial cases.

- On or before February 15, 2016, Defendants shall designate, pursuant to Fed. R. Civ. P. 26, their expert witnesses and provide their reports for each of the first six (6) bellwether trial cases.

- On or before March 1, 2016, Plaintiffs shall designate any rebuttal expert witnesses and provide their reports for each of the first six (6) bellwether trial cases.

- Each expert designation shall include at least two available dates when each expert will be tendered for deposition.

- Depositions of expert witnesses shall take place between March 5, 2016 and April 5, 2016.

Summary Judgment & *Daubert* Motions:

- Any motion for summary judgment or for partial summary judgment shall be filed on or before April 8, 2016.

- Any motions seeking to challenge an expert opinion pursuant to *Daubert* shall be filed on or before April 8, 2016.

- Responses to Summary Judgment Motions and *Daubert* motions shall be filed on May 15, 2016.

Trial Dates (for AbbVie Defendants only):

Plaintiffs propose bellwether trials for Plaintiffs suffering clotting injuries and cardiovascular injuries on the following dates:

- MDLVTE #1 (Bellwether No. 1) shall begin on June 15, 2016.
- MDL VTE #2 (Bellwether No. 2) shall begin on August 6, 2016.
- MDL VTE #3 (Bellwether No. 3) shall begin on October 8, 2016.
- MDL Cardiovascular #1 (Bellwether No. 4) shall begin on November 24, 2016.
- MDL Cardiovascular #2 (Bellwether No. 5) shall begin on December 3, 2016.
- MDL Cardiovascular #3 (Bellwether No. 6) shall begin on January 31, 2017.

Discovery on Defendants (by Plaintiffs):

- Depositions.
    - Plaintiffs have already served 30(b)(6) deposition notices on certain defendants on certain topics. The parties are conferring about the scope and content of such notices and, subject to such efforts as well as any rulings by the Court related to such depositions, it is the intent of the parties that deponents for the initial 30(b)(6) notices, including any that are served on or before September 30, 2014, will be produced for deposition on or before December 15, 2014. [9]
    - It is the intent of the parties that substantive defense witness depositions would not begin until January 2015.
- Written Discovery.
    - Plaintiffs have already propounded their First Set of Interrogatories and First Set of Document Demands to the AbbVie Defendants. Plaintiffs currently intend to propound additional interrogatories and document requests on the remaining Defendants on a rolling basis. It is understood that the written discovery propounded on the AbbVie Defendants shall be responded to in the following manner:
        - i. Interrogatory responses and reference to requested documents on or before October 31, 2014.

[9] The PSC has served five different Rule 30(b)(6) deposition notices on the AbbVie Defendants who have refused to discuss dates for these depositions. The PSC has also served one Rule 30(b)(6) deposition notice on Actavis, and today, the PSC and counsel for Actavis agreed that Actavis will produce a witness in response to this notice on December 12, 2014.

- ii. Document production and responses documents and/or databases shall be produced via rolling over which the parties will meet-and-confer. However, the rolling productions shall commence on October 31, 2014, with subsequent productions every 14 days until the production is complete.

NDA/IND:

- All Defendants shall produce their respective NDAs and INDAs in the manner they are kept and maintained in the usual course of business, or in any other fashion, subject to agreement by the parties, to the PEC on or before October 31, 2014.[10]

The deadlines summarized above provide each party with sufficient time to undertake the requisite discovery, and still have the first bellwether trial within the next two years, and a plan for five back-up trials. Moreover, the plan proposed by the PSC is a formula that has proven time and time again to be effective, and as noted above, Defendants have failed to proffer any reasonable explanation as to why this litigation is unique. There is no valid reason that would require fashioning a radically different approach, and general causation should not be decided separately and prior to all other discovery.

Not only has the general framework proposed by Plaintiffs been effective in countless other mass torts cases, this general framework is effectively endorsed by the Manual on Complex Litigation, a publication generally recognized as an authority with respect to mass tort best practices. As such, the burden to veer from the proven formula should be on the party advocating the novel approach, and this burden has not been met by Defendants here. In fact, not one reason has been proffered as to why this unique course should be adopted by this Court.

[10] As noted above, this request was made in Plaintiffs' first draft of this proposal, which was tendered on September 12, 2014. Notwithstanding this, the AbbVie Defendants believe this most rudimentary discovery need not be produced by them until 2015. *See infra* fn. 12.

With respect to the proposed trial dates in particular, because there are two disparate injury classes, the PSC respectfully submits that the Court should conduct two waves of plaintiff bellwether trials, one wave for each injury category. However, notwithstanding the separate injury categories, the discovery for both injuries should be coextensive and concurrent. Moreover, conducting discovery on both classes of injuries in related tracks will permit witnesses to be deposed on both issues at the same deposition, thereby avoiding the need to bring witnesses back for two separate depositions for each injury class.

More specifically, as identified above, the first category, clotting cases, would include venous thromboembolisms (VTEs), deep vein thrombosis (DVTs), pulmonary embolisms (PEs), ischemic strokes, and other clotting injuries. The second category, cardiac cases, would include heart attacks, strokes, and other cardiovascular injury not directly related to clotting.

To date, Defendants have avoided negotiating or discussing this concept, and instead have remained adamant about pursuing only general causation before all other issues.

In sum, Plaintiffs are prepared to address these cases in an orderly, efficient, and logical manner to achieve the Court's and the parties' objectives. However, we respectfully request that the PSC be permitted to conduct discovery in a manner consistent with the rules governing discovery in federal court, and consistent with countless other mass tort MDL pharmaceutical cases.

Finally, part of the PSC's proposal is that the first bellwether trials will be against the AbbVie Defendants only. In addition, while the PSC has not yet propounded discovery against the non-AbbVie Defendants — with the exception of one Rule 30(b)(6) notice served on Actavis — the non-AbbVie Defendants are aware that discovery against them will proceed on a track that

trails behind discovery served upon the AbbVie Defendants and will be served at time in the near future.

B. Attempts to Reach an Agreement on a Unified Case Management Plan

The PSC initially proposed its Unified Case Management Plan to Defendants on September 12, 2014. Defendants at first ignored the proposal, and then responded that it was "premature." In spite of Plaintiffs' numerous good faith efforts to meet and confer about their differences (and even ultimately having two such meetings), as noted above the parties remain fundamentally separated on essentially three issues and must seek the Court's intervention.[11]

III. Flaws with the Defendants' Proposed Unified Case Management Plan

A. Defendants' Unified Case Management Plan is Wholly Inefficient, Prejudicial to Plaintiffs, and Inconsistent with Generally Recognized Mass Tort Case Management Plans

As discussed above, the Defendants' proposed Unified Case Management Plan would require that discovery related to general causation occur prior to all other discovery, which under Defendants' plan could not begin until after this Court ruled in Plaintiffs' favor on general causation. This concept flies in the face of accepted rules regarding the parties' right to obtain relevant discovery as well as generally accepted mass tort case management plans. Furthermore, it is inefficient, will require additional expense to the parties, and, perhaps most importantly, will significantly delay the Plaintiffs right to a jury trial.

Federal Rule of Civil Procedure 26(b) provides that the parties are entitled to discovery on all materials that are relevant to any party's claim or defense. FED. R. CIV. P. 26(b). The Federal

[11] Should the Court be inclined to review the ongoing correspondence related to the attempts to reach an agreement on a Unified Case Management Plan, Plaintiffs are happy to submit a number of emails and other evidence showing Defendants' reticence in this process and delays in providing both comments to drafts as well as delays in the meet-and-confer process.

Rules support the PSC's position that it is entitled to conduct discovery on issues other than just general causation. Similarly, and as discussed above, the Defendants' proposed approach of requiring general causation discovery to be conducted first and in a vacuum is a novel approach that the PSC respectfully submits should not be adopted absent some compelling reasons (which are not present here) for such a drastic approach.

Similarly, the concept of conducting general causation discovery first while delaying all other discovery is extremely inefficient. As discussed above, staggering each stage of discovery will increase the time that it takes to get to trial, and is simply a veiled attempt by Defendants to thwart and delay Plaintiffs' right to trial. Conversely, by conducting concurrent discovery (liability, bellwether and causation), the parties and the Court's time from inception to trial in this litigation will be minimized, which will have the ultimate effect of decreasing Court and attorney time and expenses.[12] This is an overall benefit for all involved in this MDL.

Finally, it is undeniable that the Defendants' Unified Case Management Plan wholly prejudices Plaintiffs, who under this plan would be forced to wait over three years before the first trial was to occur (and even then, the defense only allots for two trials), and forces a disjointed inefficient overall discovery schedule. There is simply no reason for this obstruction to the Plaintiffs' pursuit of justice when the parties are perfectly capable of conducting concurrent discovery, and thereby shortening the time to trial by approximately a year. Finally, staggering this litigation in the way suggested by Defendants would also prejudice the Plaintiffs in their efforts to conduct discovery regarding the liability aspects of this case against these Defendants.

[12] As noted herein, the PSC and the Defendants are essentially in agreement that *Daubert* motions can be conducted by the Spring of 2016. However, the defense proposal has nothing else ready by this time, whereas the PSC proposes that the entire case be ready at this time.

A thorough review of Defendants' proposed Uniform Case Management Plans shows that in the initial discovery stage, Plaintiffs would be entitled to discovery and inquire only into questions of "general causation," which Defendants define as information showing that testosterone products cause cardiovascular injuries.[13] When this general causation discovery is completed, Defendants would then be permitted to challenge, via *Daubert* motions and summary judgment motions, matters of general causation only.

In Defendants' third phase, and when Plaintiffs defeat *Daubert* and/or summary judgment motions related to general causation, a formal bellwether process would commence (meaning plaintiff-specific discovery). Pursuant to Defendants' plan this would not occur until July 15, 2016 at the earliest — virtually guaranteeing that this MDL will last at least five years. During this later phase, Plaintiffs would then be permitted to commence discovery on issues other than causation, including critical issues such as marketing, sales, promotion, and other topics that are likely partially covered in "general causation discovery" (which Defendants propose limiting to "regulatory affairs," "medical affairs," and/or "pharmacovigilance").[14]

[13] Curiously, if in fact Defendants were serious about the front-loading of general causation discovery, they have done everything in their power to prevent the PSC from pursuing this discovery. The PSC has been completely stonewalled by the AbbVie Defendants in all efforts to begin the discovery process. The AbbVie Defendants have essentially refused to begin negotiating a timeline for responses to interrogatories or document requests (both of which were propounded nearly 60 days ago). The AbbVie Defendants have also refused to discuss scheduling initial 30(b)(6) depositions, or even discuss a reasonable timetable to produce the NDA/INDA (something that can and should be readily produced within days of a request). The AbbVie Defendants have repeatedly relied on the mantra that the Court said "we don't have to" begin participating in discovery by setting deposition dates. The AbbVie Defendants have also used the fact that the Court has yet to rule on the motion relating to the format of production to refuse to produce any documents, even those that are not going to be impacted by the format of production issue such as documents that exist in paper hard copy format. These delay tactics underscore that Defendants' request for general causation to be front-loaded, and for only limited discovery to be allowed, is nothing more than the age-old tactic of Defendants to delay as much as possible. If in fact the AbbVie Defendants were serious about wanting to defend their product and prove their product is safe, it surely would have buttressed its argument by at least allowing Plaintiffs to start the discovery process, rather than thwart all efforts (including efforts at scheduling conferences to resolve disputes without Court intervention).

[14] Defendants' proposal seeks to exploit the very nature of pharmaceutical cases to their advantage. They know full well that all of these areas of discovery are intertwined with the science of the case — in fact the PSC fully expects

Following this discovery, Defendants propose that yet another wave of dispositive motion practice would ensue (likely against many of the same experts who would need to issue new reports, be re-deposed and now opine on matters related to specific causation). Finally, as noted above, the Defendants would have the first trials occur in December 2017 — more than three years from now. Although Defendants have demonstrated a willingness to adjust some of the dates from their original plan, which had the first trial in 2019, they have also flatly informed Plaintiffs that they will not negotiate on the issue of front-loading general causation or bifurcating[15] the discovery against each of the Defendants.[16]

As discussed in further detail below, front-loading general causation will not foster efficiency in this MDL, nor will bifurcating Defendants' discovery, or staggering plaintiff

to hear the corporate mantra of "we only market within the label" repeatedly, but the PSC also fully expects to prove that this is not the case. Defendants' true intent here is to prevent the PSC from discovering evidence that tends to paint the company in a not-so-flattering light on science and marketing issues. It is common that while the company is internally saying one thing about the science, they are downplaying those same risks with the FDA and foreign regulatory authorities — often telling them different things — as well as the medical community. Bifurcating discovery will result in corporate witnesses being deposed multiple times in this MDL if the PSC is not provided regulatory, medical affairs, and marketing information at the time the scientific witnesses are originally deposed. For example, the PSC should not be deprived of the opportunity to ask scientific witnesses if certain marketing and/or regulatory statements are truthful regarding the scientific facts. Defendants' proposed plan sets this case up for re-deposing of witnesses. Perhaps that is intentional as Defendants may believe that they will be able to "clean up" any problems with the first deposition, but such gamesmanship should not be countenanced by the Court.

[15] Bifurcation of discovery is a disruptive attempt to delay this MDL's progress and would also likely derail the Court's objectives. As discussed more fully herein, it would also be an enormous waste of time and resources having to conduct case-specific expert discovery after limited general discovery as the defense proposes. Indeed, it is highly likely that both sides will have general causation experts who will opine about both general causation issues and case-specific causation issues. For example, a hematologist will likely opine about general causation as it applies to these products causing blood clots and, also, how a given product caused a given plaintiff's blood clot. Similarly, we suspect cardiologists will provide the same general testimony as it pertains to heart attacks as well as case specific causation. As such, there will be a tremendous waste in having these experts (for both sides) deposed twice, and thus having to issue additional reports, and then perhaps having additional *Daubert* motions and hearings.

[16] The PSC believes Defendants' unwillingness to negotiate indicates a lack of good faith in this process. Indeed, the PSC did not propose concepts like reverse bifurcation for punitive damages to proceed first, or to have the first trial be a joint trial of 10-12 plaintiffs despite the fact that there is support for such novel procedures.

discovery. In fact, the likely effect will be the opposite. Defendants' proposal will cause delays, inefficiency, increase costs for both sides, and will prejudice Plaintiffs (as the PSC has a right to conduct discovery in a manner it deems appropriate and warranted, and not as Defendants dictate).

B. Front-Loading the Issue of General Causation Is Not Appropriate

As has been discussed at length above, the concept of limiting discovery related to general causation only and occurring first, to the exclusion of all other discovery is novel and unwarranted. In fact, the Defendants' proposed Uniform Case Management Plans fails to identify any reasons why this approach would be warranted here. At a bare minimum, Defendants should be required to articulate some valid reason that this inefficient and unusual case management plan should be used.

Although a very small number of courts have actually bifurcated the general causation question, when it is done it is generally only in cases where developments during the pending litigation have made the burden of general causation a seemingly impossible task.[17] That is not the case here where the medical literature and/or the epidemiology is replete with articles and studies identifying a significantly increased risk of cardiovascular events associated with testosterone containing products, a recent FDA mandated label change to add a heightened warning about the risk of blood clots, and a recent FDA Advisory Committee vote that recognized the dangers in these products and that these products are being improperly prescribed.

Proceeding in the standard manner with full case discovery, as is generally done, does not prejudice Defendants in any way. Simply put, Defendants have not demonstrated that a normal case progression (*i.e.*, that which is proposed by the PSC) would prejudice them. Defending against

[17]*See e.g., In re Bendectin Products Liability Litigation*, 732 F. Supp. 744 (E.D. Mich. 1990) (MDL No. 85-0996) (the Court bifurcated the question of general causation due to emerging developments rendering general causation more difficult to prove).

properly made allegations and conducting full blown discovery with an eye towards setting trial dates is not prejudicial, it is the norm. In fact, as discussed in more detail herein, Plaintiffs would be prejudiced by the proposed bifurcation of discovery. Additionally, bifurcation would undermine judicial economy in this case, not promote it. In short, it is the position of the PSC that conducting general causation discovery first would severely prejudice both Plaintiffs and the PSC by not providing them the opportunity to fully pursue discovery, and by significantly delaying Plaintiffs' right to trial.

Interestingly, while the Defendants are on the one hand asking the Court to halt all non-general causation discovery, they have repeatedly asked the Court to accelerate the entry of the case management order governing the Plaintiff Fact Sheet. Defendants not only pushed for the PFS to be completed and urged the PSC and Court of its critical importance to the case, they even made plans to ensure that there would be no delays in obtaining missing PFS's (*see* CMO No. 7 at II.E), curing allegedly deficient PFS's (*see* CMO No. 7 at II.D), and even in collecting records for all of the Plaintiffs.[18] Defendants' position with respect to the PFS undermines their current position that plaintiff-specific discovery should be halted and/or that it is too expensive to undertake.

C. Bifurcation of Defendant Discovery Will Cause Inefficiencies for the Court and Parties and Will Cause Significant Additional Delay

[18] In the jointly agreed CMO that accompanied the PFS, the Defendants requested the following language (underscoring their desire to immediately work on the cases and spend money gathering medical records):

> Upon receipt of a completed PFS and/or any information identifying a plaintiff's healthcare providers, employers, disability providers, and/or insurers, MRC, at Defendant(s) request, may immediately undertake to obtain those records by use of the written authorizations that are provided. *See* CMO No. 7 at IV.B

Defendants propose a year of only general causation discovery followed by nearly a year of "general causation proceedings" in which they might bring a variety of *Daubert*-based dispositive challenges, and during which time no other discovery is conducted. *See* Ex. B at §1; Ex. C at §1; Ex D at ¶¶2-3. There can be no denying that this will delay both the bellwether process and the entire litigation. Moreover, it is wholly inefficient to require that each topic area of discovery be undertaken and completed before the next topic area of discovery starts. Defendants have shown no likelihood they will succeed with respect to these general causation/*Daubert* motions, thus rendering it entirely illogical to not proceed with general discovery. Even assuming a 50/50 likelihood that Defendants would prevail with respect to general causation, which the PSC strongly disputes,[19] even with those odds it is still more advantageous to conduct discovery on all the issues in the case as a whole rather than piecemeal, and prepare actual plaintiff's cases for trial as part of a bellwether process.

In addition, because "general causation" discovery is a concept that is being defined by Defendants as they go, it seems highly likely that countless motions regarding the scope of "general causation" discovery will be put before the Court, which will require briefing and/or hearings. This will further delay the discovery process. In short, the result of Defendants' proposal is disruptive and counter-productive, and will fail to achieve any positive objective.

D. Defendants' Proposal is Disingenuous

An examination of the Defendants' proposal and their current labels reveals that the Defendants' claim that they want to stagger each stage of discovery so that they can challenge

[19] As set forth below, the issue of general causation is not as much in question as Defendants would like to have the Court believe. First, Defendants' own package insert already identifies the blood clotting risks associated with the use of testosterone products, which is strong evidence of a causal connection. With respect to cardiovascular risk, although no warning is currently on the package insert relating to this risk, the panel members at the FDA Advisory Committee meeting, held on September 17, 2014, which considered the cardiovascular risk associated with testosterone products, voted by an overwhelming majority that the medical literature reveals a safety signal with respect to the risk of cardiovascular events associated with the use of testosterone products.

general causation is disingenuous. As demonstrated below, their true motive for staggering discovery can only be described as delaying the progress of this litigation and frustrating Plaintiffs' discovery efforts.

1. Defendants Already Admit General Causation

Defendants define cardiovascular injuries as including "heart attacks, strokes, arterial or venous thromboembolic events, and any other cardiovascular injury." *See* Ex. D at ¶1. As noted above, each Defendant already warns against blood clots in their respective package inserts as a result of a recent FDA-mandated label change. While Plaintiffs submit that the warnings relating to blood clots are, and always have been, insufficient, Defendants' warnings regarding blood clot risk associated with testosterone therapy is significant evidence of biological plausibility and general causation.

Thus, it is disingenuous of Defendants to tell the Court they need two years to methodically challenge whether Plaintiffs can prove testosterone therapy causes the very thing they currently warn about.

2. *Daubert* Challenges Should be Considered After the Completion of Generic Discovery

Notably, Plaintiffs' proposed schedule does not preclude Defendants from making *Daubert* motions at the close of expert discovery as is done in most cases. Plaintiffs disagree with spending two years isolating the general causation issue, which Defendants have already raised in their pending motion to dismiss, to the exclusion of all other discovery.

3. The FDA is Currently Considering Whether Testosterone Replacement Therapy is Correlated with Cardiac Events (as well as the overall efficacy of Testosterone Replacement Therapy)[20]

On September 17, 2014, an FDA Advisory Committee panel heard testimony from industry representatives, independent medical experts, and men gravely injured by testosterone replacement therapy concerning the risk of cardiac events associated with testosterone replacement therapy.[21] The result was nearly unanimous: the panel recommended overwhelmingly that the FDA compel testosterone replacement therapy manufacturers (these same Defendants) to conduct more extensive research on the correlation between testosterone replacement therapy and cardiac events.

Allowing Defendants to isolate the issue of general causation may produce a result that is inconsistent with that of the FDA reexamination of the cardiac risk associated with testosterone products. The FDA's process of reexamining testosterone replacement therapy's link to cardiac

[20] It is important to note that while testosterone was only approved for men diagnosed with primary or secondary hypogonadism, it has been primarily marketed to and used by men who do not have that condition but instead merely have a normal, age-related decline in testosterone levels. At the FDA Advisory Committee meeting on September 17, 2014, the panel of physicians noted that there is a complete lack of data to demonstrate that testosterone therapy confers any benefit to men who do not have a diagnosis of hypogonadism. The panel voted 20-1 in favor of changing the label to clearly state that testosterone is not approved for an age-related decline in testosterone. The panel further opined that any risk of injury associated with the use of testosterone is unacceptable and must be warned against in light of the fact that there is no proof that the drugs provides any benefit. As such, the proof of which risks can be associated with the use of testosterone generally (aka "general causation") is completely related to those that are not outweighed by the benefit conferred by the use of the drug. It would be impossible to somehow extricate discovery and proof solely on the issue of general causation from the overall theory of liability because of the manner in which the drug was marketed to a population for whom it was never FDA approved and provides no benefit.

[21] This FDA panel, comprised of experts in various disciplines were invited by the FDA to consider issues related to the use of testosterone therapy, and made recommendations to the FDA concerning the appropriateness of the labeling of testosterone products as well as the need for manufacturers to conduct further studies regarding the association between testosterone products and cardiovascular risk. While the findings of the panel are not binding on the parties in this litigation, nor is the FDA required to follow the panel's recommendations, the initial message from the panel of experts was clear that there is the potential for risk associated with testosterone products, and there is no evidence of benefit of these drugs for men suffering from age-related hypogonadism, a population for which these drugs are not approved.

events may reveal a correlation that could lead the FDA to compel Defendants to warn consumers of the cardiac risks as they presently do with respect to the clotting risk.

E. Defendants' Proposal Would Prejudice Plaintiffs by Greatly Raising Costs for Both Sides

Before Plaintiffs can properly oppose a *Daubert* or summary judgment motion, they need, and are entitled to, sufficient discovery. This includes all documents and testimony potentially relevant to the question of general causation, such as Defendants' internal studies, their opinions and/or interpretations of those studies (from any relevant custodians), as well as materials related to how Defendants interpreted and/or reacted to cardiac events that occurred in any of those internal studies (again, from any relevant custodians). Many of the witnesses who would need to be deposed with respect to these general causation issues will likely wind up being deposed in Defendants' proposed second phase of discovery as well, thereby increasing costs to the Plaintiffs.

Further, if the Court were to opt to separate non-clotting cardiac events (the question the FDA is currently considering) from clot-based events (which Defendants cannot, in good faith, argue against since they already warn of clots), the Court would end up creating three discovery plans: a discovery plan on everything related to clotting events (including marketing, drug approval, internal studies, general causation, and specific causation); a discovery plan related to just general causation on non-clot cardiac events; and a third discovery plan after Plaintiffs prevail on the non-clot cardiac general causation question. Each discovery plan necessitates expert reports, document review, deposition prep, and depositions. But, much of the evidence and many of the people will be common rendering such discovery staggeringly expensive and inefficient.

Finally, and quite ironically, we suspect the AbbVie Defendants will argue that front-loading general causation, and bifurcating discovery would actually save costs. This argument is misplaced and specious.

F. The Confusion Created by the Adoption of the Defendants' Plan May Diminish the Objectives of Consolidation

A two-year delay in these consolidated proceedings to allow Defendants to challenge a limited facet of Plaintiffs' case also has the potential to diminish the PSC, and Plaintiffs' leadership's ability to properly guide this litigation by limiting their ability to discover the full liability case. Moreover, this two-year delay will also diminish one of the main objectives of multidistrict litigation, namely, efficiency, and thus may drive some plaintiffs to state court venue.

Since the time the Judicial Panel on Multidistrict Litigation ("JPML") centralized these cases to this Court, and even before, the Court has expressed an interest in the leadership representing a wide cross section of the plaintiffs' bar, presumably, among other things, to avoid encouraging factions of plaintiffs' attorneys from prosecuting this litigation in a wide variety of forums and defeating the JPML's purpose in centralization. The PSC is committed to this MDL and ensuring this Court and these cases stay in the forefront.

By front-loading general causation, this objective of efficiency will likely be diminished by virtue of the fact that it will cause unacceptable delay in obtaining resolution of this litigation, and this may encourage plaintiffs lawyers to file their cases in alternative state court venues. As such, for these reasons as well, the PSC respectfully submits that the Defendants' Uniform Case Management Plan should not be adopted by this Court.

IV. Conclusion

In light of the foregoing, Plaintiffs respectfully request the Court adopt Plaintiffs' proposed Uniform Case Management Plan, and deny Defendants' proposed case management schedule that bifurcates discovery and front-loads the issue of general causation.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Brian J. Perkins, hereby certify that on October 20, 2014, I electronically transmitted a true and exact copy of the foregoing document, to the Clerk of the Court using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to all attorneys of record who are ECF registrants.

/s/ Brian J. Perkins